CASE REPORT/CASE STUDY

Unit: Human Research Protections Program (HRPP), Office of Research
Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:
N/A

DEFINITIONS:
A *Case Report* is the retrospective review of a single patient's clinical course and usually includes a literature review related to the noteworthy aspect of the case. It is the account of "an interesting person with an interesting issue/problem." A case report may provide clues in identifying a new disease or adverse health effect from an exposure. It is most likely to be useful when the disease is uncommon and caused exclusively or almost exclusively by a single kind of exposure. A case report has no hypothesis, data analysis, or generalizable conclusion. A Case Report does not require IRS submission.

- If a clinician considers preparing a case report of a patient still under his/her care, he/she must distinguish between "routine care" (i.e., care routinely provided to similar patients) and "extra care" provided to enhance academic interest in the final case report (e.g., extra lab tests, extra imaging). The initiation of any "extra care" makes this activity, "human subject research" requiring IRS review and approval.

A Case Study is a qualitative research method. It is the in-depth analysis, empirical inquiry, or investigation of a person or group in a natural, uncontrolled setting. This research method is done from the participants' perspective and studies how they make meaning of the world – not how researchers manipulate it. Qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them.

A case study includes multiple data sources such as interviews, documents, archival records, direct observations, and physical artifacts. Analysis is through description, themes, and assertions. Researchers from many disciplines (e.g., social/behavioral, educational, epidemiological) use this method to build upon, produce new, and dispute current theory. A Case Study requires IRS submission.

*NOTE: A Case Series is a group of Case Reports and may require IRB submission. Per the following criteria:
- A Case Series which consists of 3 or less Case Reports does not require IRB submission
- A Case Series which consists of 4 or more Case Reports will require IRB submission.
PROCEDURE:
N/A

REFERENCES:
N/A

ATTACHMENTS:
N/A

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Approved By: [Signature]
David Clark, PhD, Assistant Dean for Clinical Research and Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin